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U.S.

High Cost of New Hepatitis C Drugs Strains Prison Budgets, Locks Many Out of Cure

Thousands of convicts have the deadly infectious disease, but only the sickest qualify for medicines because they are so expensive

By PETER LOFTUS and GARY FIELDS

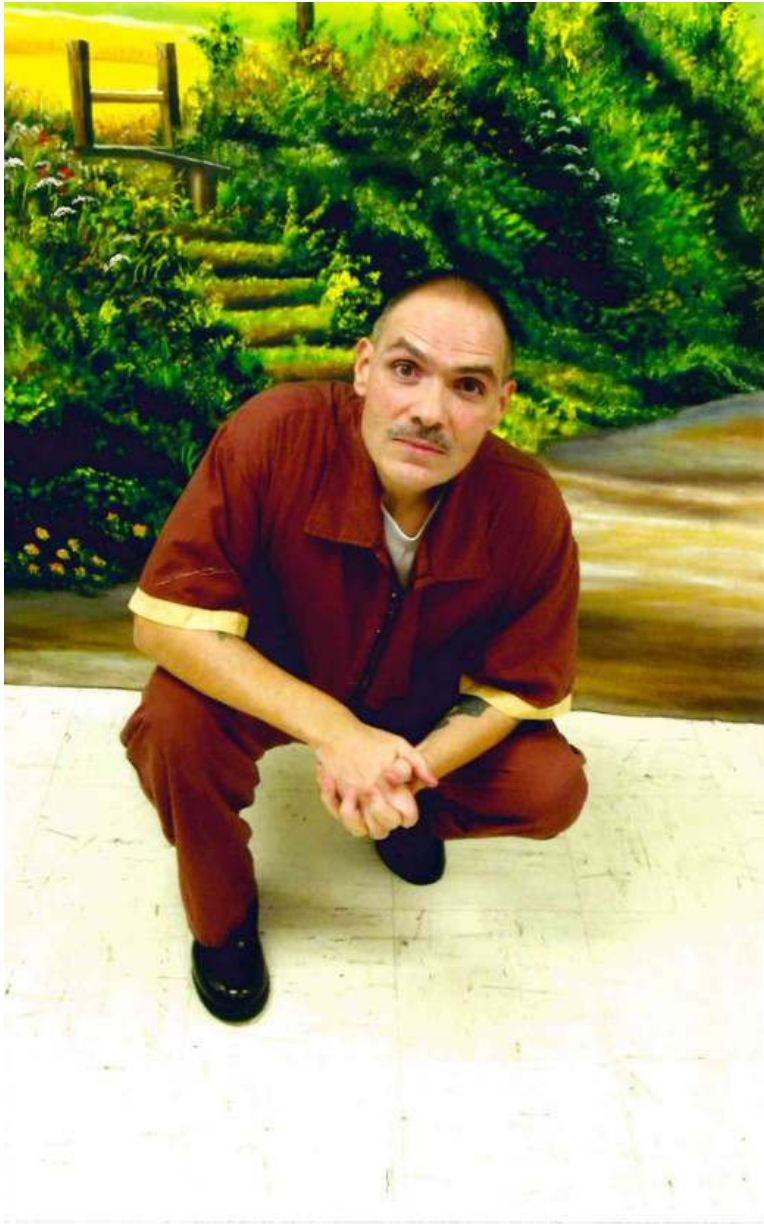
Sept. 12, 2016 1:34 p.m. ET

GRATERFORD, Pa.—David Maldonado, an inmate at a Pennsylvania state prison, is one of thousands of convicted criminals with hepatitis C, an infectious disease that is one of the country's biggest killers. Powerful new drugs on the market could help Mr. Maldonado and cut the chances of it spreading outside prison walls.

The medicines, however, are so expensive, and the problem so widespread, that to treat all sufferers would blow up most prison budgets. List prices for the newer drugs range from \$54,000 to \$94,000 a person for a typical 12-week course.

Pennsylvania's corrections department has given the drugs to inmates at high risk of developing liver problems and with low blood-platelet levels. Mr. Maldonado isn't among them, because his disease isn't advanced enough to meet the department's criteria, and he has sued seeking treatment.

In a March court filing, the department said treating the state's estimated 7,000 infected inmates would cost about \$600 million, which "would effectively cripple the Department from a budgetary standpoint" and squeeze other medical care and security needs. A spokeswoman declined to comment on Mr. Maldonado's case.



Graterford prisoner David Maldonado, who suffers from hepatitis C, is suing the Pennsylvania prison system seeking access to a new, expensive class of drugs. *PHOTO: FROM DAVID MALDONADO*

The rationing, which has been implemented at both the state and federal level, is an acute example of the dilemmas caused by both high and fast-rising drug prices. Lawmakers and consumers have increasingly pressured drugmakers such as Valeant Pharmaceuticals International Inc. and Mylan NV over the prices they charge, and both presidential contenders have proposed ways to cut them.

California's Department of Corrections and Rehabilitation said costs for hepatitis C medication totaled \$66 million in the year ending June 30, compared with \$47 million the year before. The increase stemmed more from a jump in cost per treatment than from an increase in the number of patients being treated.

In Alaska, about 1,800 of the 4,624 inmates on any given day have hepatitis C, said Robert Lawrence, chief medical officer for the Alaska Department of Corrections. Treating them all would cost nearly three times Alaska's \$40 million annual prison-system health-care budget.

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"If we can treat them they won't go back into the community and spread it further," he said. "That's the solution, but here is the problem—the cost of the drug."

The hepatitis C virus, which has infected between 2.7 million and 3.9 million Americans, kills more people in the U.S. than HIV and dozens of other infectious diseases combined, according to the Centers for Disease Control and Prevention. Unlike many diseases, hepatitis can take 20 to 30 years to advance to a life-threatening stage, sickening patients and risking transmission to others all the while.

Prisoners have a higher infection rate because many have a history of injection drug use, a common route of the blood-borne virus's transmission. Researchers at Emory University estimate that at least 17% of the nation's 1.3 million state prisoners have the disease, compared with about 1% of the general population.

The new treatments, including Gilead Sciences Inc.'s Sovaldi and Harvoni, AbbVie Inc.'s Viekira Pak and Merck & Co.'s Zepatier, began to reach the market about three years ago. They are shown to have cure rates above 90% while reducing side effects and cutting treatment times to about three months on average.

Older medicines have cure rates of about 65% or less and need to be taken for up to a year. Some have been discontinued by manufacturers. When they are prescribed, it is generally in combination with the newer drugs.

Patients with private health insurance and those relying on state Medicaid programs have also had difficulties getting the newer drugs, although some of those restrictions are being eased. In August, Massachusetts made the drugs more widely available after negotiating a lower price with Gilead.



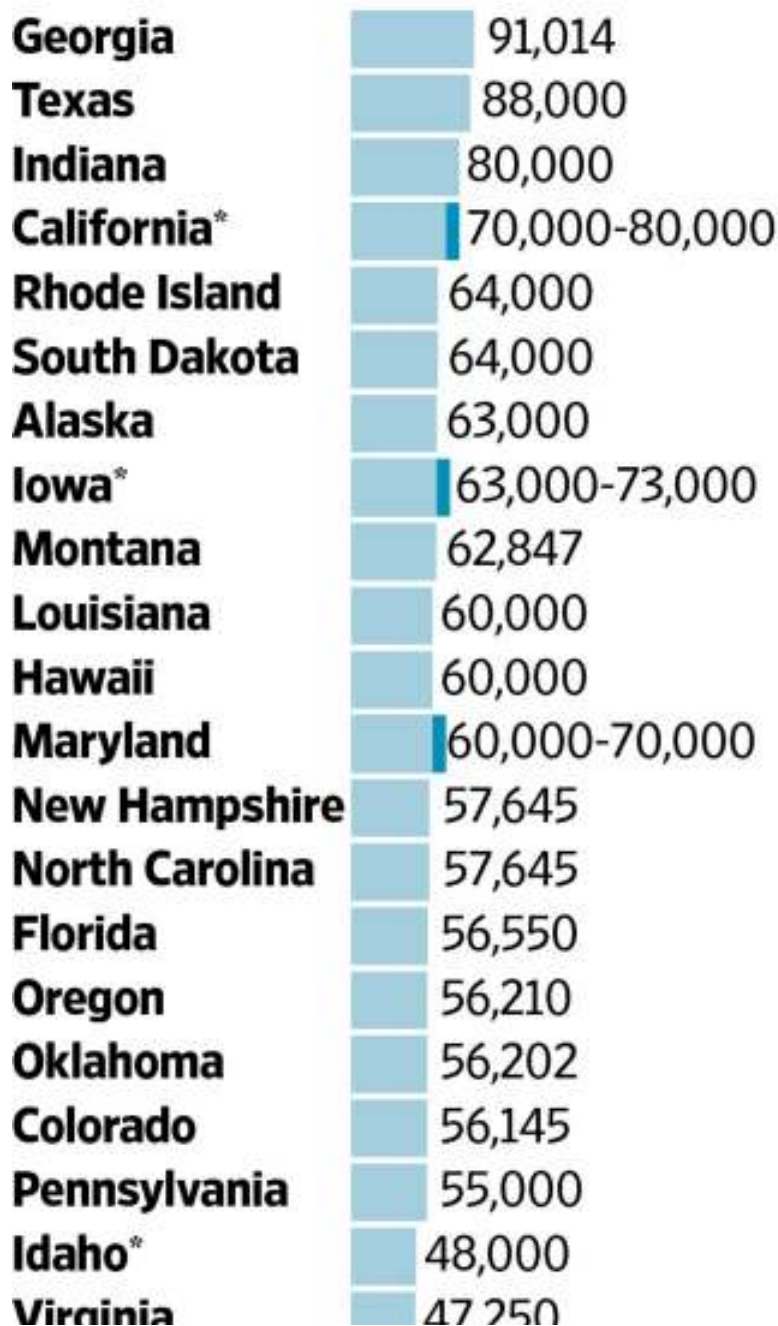
Inmates wait their turn at the infirmary at Graterford prison. *PHOTO: RYAN COLLIERD FOR THE WALL STREET JOURNAL*

State prisons say they are modeling policies after the federal prison system, reserving drugs for the sickest patients while monitoring the health of other infected inmates. Gabriel Eber, senior staff counsel for the American Civil Liberties Union national prison project, said he can't think of another example of drugs used to treat a large-scale epidemic being rationed because of their cost.

Such withholding is at odds with treatment guidelines from medical societies, which recommend most people with persistent hepatitis C be given new drugs, regardless of the stage of their disease.

A Costly Cure

The per-patient price paid by state corrections departments for a 12-week course of Gilead Sciences Inc.'s hepatitis C drug Harvoni.



“While we realize that certain patients with advanced liver disease do need the treatment more quickly, that does not abrogate the responsibility to treat patients at earlier stages of disease,” said Dr. Arthur Kim, an infectious-disease specialist at Massachusetts General Hospital in Boston who helped draft the treatment guidelines. “We would never not treat diabetes until there were later complications.”

North Dakota 46,021

*Costs include Harvoni and other newer medications.

Source: state corrections departments

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The Wall Street Journal surveyed all 50 state departments of corrections to determine how many affected inmates are receiving newer hepatitis C drugs.

The 34 states that had

data reported a total of roughly 101,000 inmates with the condition. Of those, about 3.4% have been treated for hepatitis C with the new drugs. A few states provided estimates of prevalence and treatment rates only. The remaining states didn't have the data, or declined to comment. Some didn't respond to phone calls or emails.

The majority of responding states cited cost as a reason for limiting treatment. Few prisoners have private insurance, and federal law generally prohibits Medicaid from funding most types of inmate care that doesn't require hospitalization.

The nation's 192 federal prisons are also feeling the squeeze, despite access to mandatory drug discounts.

Federal Bureau of Prison spending to treat hepatitis C has tripled since 2013, even though the number of treated patients has fallen by 42%, according to a bipartisan report from December issued by members of the Senate Finance Committee.

Last year, the system treated 222 inmates, the vast majority with the new drugs, out of an estimated infected population of 9,200. A Bureau of Prisons spokesman said the number treated declined because the bureau reserved the new drugs for its sickest inmates and delayed treatment for others.

The bureau said it receives an average discount of 38.4% off the list prices for the new hepatitis C drugs, using Department of Veterans Affairs contracts. State prison systems, which house the majority of U.S. prisoners, aren't entitled to those discounts.

The Senate Finance Committee, as part of its investigation into the pricing of Sovaldi and Harvoni, has charged that Gilead, of Foster City, Calif., made decisions knowing they would put the drugs out of reach for many patients.



Gilead Sciences Inc.'s Harvoni is one of the new breakthrough drugs for hepatitis C. *PHOTO: LLOYD FOX/TNS/ZUMA PRESS*

A Gilead slide deck for an internal presentation in September 2014, released by the committee, showed plans to offer discounts of 10% to 20% for Harvoni to prison health-care programs in just seven states, including California and Texas, because they had high infection rates. The Senate report concluded Gilead “saw diminishing benefits in smaller prison systems.”

Michele Rest, a spokeswoman for Gilead, said the company offers discounts to large and small prison systems, sometimes directly, or through pharmacy-benefit managers or multistate purchasing groups. Gilead said prisons can partner with hospitals for certain discounts, which would put the price on a par with rates for state Medicaid programs.

“This isn’t a system we’ve ignored,” said Coy Stout, Gilead’s vice president of managed markets.

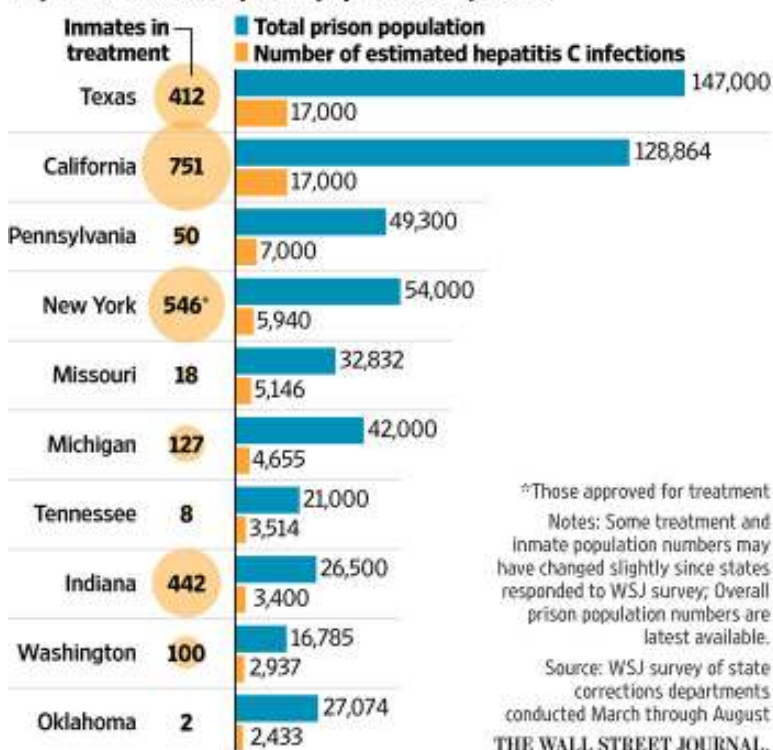
Gilead dominates the market for new hepatitis C drugs, collecting more than \$19 billion in annual revenue from such sales last year. Its U.S. list prices of \$1,000 per pill and higher for Sovaldi and Harvoni have drawn criticism from insurers as well as state and federal officials.

“We have seen increased concerns about the cost of recent drug approvals that really have forced states to re-allocate resources to cover those drugs,” including Sovaldi, said Pam Curtis, director of the Center for Evidence-Based Policy at Oregon Health & Science University, which helps state Medicaid programs decide what drugs they will cover.

Many Infected, Few Treated

Newer drugs for hepatitis C have high cure rates—and high price tags to match. The cure/cost disconnect, doctors warn, is fueling a public-health crisis, especially in prisons. A Wall Street Journal survey of state corrections departments illustrates the problem.

Hepatitis C-infected prison populations by state



AbbVie and Merck, which also sell expensive new treatments for hepatitis C, say they too are working with prison systems to make their drugs more available to inmates. They declined to disclose details about the terms of their contracts with state prisons. The list price for AbbVie's Viekira Pak is more than \$83,000 for a 12-week course, while Merck's Zepatier is \$54,600 for a 12-week treatment.

According to court records, when he was 17, Mr. Maldonado stabbed and killed a 19-year-old man near a Philadelphia

swimming hole called Devil's Pool in August 1980.

"I can apologize a thousand times, but still I can never change what happened. I wish I could," Mr. Maldonado, now 53, said in an interview at Graterford prison, which is about 30 miles northwest of Philadelphia. He was sentenced to life without parole.

A prison doctor diagnosed Mr. Maldonado with hepatitis C in 1997, after he began to experience joint stiffness. Mr. Maldonado said he probably got the virus from injection-drug use or the tattoos he received in jail.

Prison health officials tried to cure him with older drugs in 2001 and 2013, but the virus persisted. Mr. Maldonado said he kept tabs on the newer drugs by subscribing to a hepatitis C newsletter. He began asking the prison's medical staff for Gilead's Harvoni soon after it came out in late 2014.



Inmates at Graterford prison clean their cell block. *PHOTO: RYAN COLLARD FOR THE WALL STREET JOURNAL*

In June 2015, with the help of the Pennsylvania Institutional Law Project, which provides free legal services for prisoners, he filed suit in federal court seeking access to the drugs for himself and other infected prisoners. The suit contends that denying access to the latest treatments is a violation of the Eighth Amendment, which prohibits cruel and unusual punishment of prisoners. Similar lawsuits are pending in Minnesota, Tennessee and Massachusetts.

“Our punishment is being removed from society, not being denied medical care,” said Mr. Maldonado.

This past April, Mr. Maldonado's lawyer received an email from the corrections department's attorney saying he didn't meet the criteria for the new drugs. The case is pending.

Write to Peter Loftus at peter.loftus@wsj.com and Gary Fields at gary.fields@wsj.com

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